IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE BAUSCH & LOMB INC. CONTACT LENS SOLUTION PRODUCTS LIABILITY LITIGATION	**Management File No. 2:06-77777 DCN**
(1) ENERY FERNANDEZ PIÑERO, her husband GERARDO SUAREZ MERCADO, and the LEGAL CONJUGAL PARTNERHISP formed by them; (2) JOSE DAVID PEDROGO, his wife NEIDA DE-LAJARA BORELLI, and the LEGAL CONJUGAL PARTNERHISP formed by them; (3) MARIA **ADORNO DÁVILA; (4) MANUEL CLASS CASTRO** and the LEGAL CONJUGAL PARTNERHISP formed by him and his wife; (5) JUAN CARLOS PEREZ RUIZ his wife OMAYRA RIOS MUNOZ and the LEGAL CONJUGAL PARTNERHISP formed by them; (6) ROLANDO PEREZ VARGAS and his mother SONIA VARGAS PEREZ; (7) OSCAR PEREZ VARGAS and his mother SONIA VARGAS PEREZ; (8) LUISA VEGA RAMOS, her husband JAVIER MARTINEZ CORTES and the LEGAL CONJUGAL PARTNERHISP formed by them; (9) YARITZA VILLEGAS DIAZ; (10) HIRAM MALDONADO and MARGARITA HEREDIA on their own and on behalf of their minor daughter HIRMAR MALDONADO HEREDIA; (11) LILLIAM TRISTANI RODRIGUEZ; (12) MADELINE CALDERON COLON; (13) ADALYZ RODRIGUEZ PIZARRO her husband NELSON RODRIGUEZ and the LEGAL CONJUGAL PARTNERHISP formed by them; (14) MAGDALENA RODRIGUEZ RAMOS on her own and on behalf of her minor daughter FRANCYS PEREZ RODRIGUEZ; (15) EDGARDO ROBLES DAVILA, his wife RUTH BIDOT BAERGA and the LEGAL CONJUGAL PARTNERHISP formed by them; (16) ELISA PEDROZA GOMEZ, her husband ANGEL RIVERA RODRIGUEZ and the LEGAL CONJUGAL PARTNERHISP formed by them husband JOSE TORRES GONZALEZ and the LEGAL CONJUGAL PARTNERHISP formed by them;	**MDL Docket No. 1785** **This filing relates to the related civil action No. 2:06-2702**

(17) MAYRA GOMEZ TORRES her husband LUIS VELAZQUEZ ALAMO and the LEGAL CONJUGAL PARTNERHISP formed by them; (18) RAFAEL RIVERA SANCHEZ; (19) MARIELA FRIAS APONTE her husband JOSE TORRES GONZALEZ and the LEGAL CONJUGAL PARTNERHISP formed by them; (20) GIOVANNI MARCANO MORAN his wife MAYRA CABRERA BATISTA and the LEGAL CONJUGAL PARTNERHISP formed by them; (21) WILMA MIRANDA PEÑA; (22) ELBA DAVID PEDROGO, her husband RAMÓN MATOS RIVERA and the LEGAL CONJUGAL PARTNERHISP formed by them; (23)JUAN CANCEL MONTES, his wife JENNIFFER ORTIZ and the LEGAL CONJUGAL PARTNERHISP formed by them; (24) ALBERTO DE HOWITT PEREZ; (25) LYDIA CRESPO RUIZ; (26) YOCELYN GONZALEZ CRESPO; (27) MIGDALIA GUADALUPE HERNANDEZ; (28) EILEEN MARQUEZ CASTILLO, her husband SEBASTIAN INSANZON and the LEGAL CONJUGAL PARTNERHISP formed by them; (29) HENRY MEDINA ATECA; (30) JOEL RIVERA RIVERA; (31) EVANGELINA RODRIGUEZ FELICIANO, her husband RICHARD GUZMAN RIVERA and the LEGAL CONJUGAL PARTNERHISP formed by them; (32) ROSA SANTOS CRUZ; (33) CARINA VAZQUEZ ESCODA, and her consensual companion RICARDO DIAZ CRUZ; (34) ENID MALAVE CRUZ, and her consensual companion HECTOR PEDROSA LUNA

Plaintiffs

v.

BAUSCH & LOMB INCORPORATED

Defendant

FIFTH AMENDED COMPLAINT

TO THE HONORABLE COURT:

COME NOW plaintiffs, by and through the undersigned counsel, and respectfully allege, state and request, as follows:

I. JURISDICTION

1. This Honorable Court has jurisdiction over the parties and the subject matter of this litigation pursuant to 28 U.S.C. Section 1332, because all the parties on either part of the controversy are of diverse citizenship and the amount in controversy exceeds the sum of Seventy Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

2. The facts set forth in this complaint are actionable under Articles 1802, *et. seq.*, of the Civil Code of Puerto Rico, 31 L.P.R.A. Sections 5141, *et. seq*..

3. Venue is proper in the United States District Court for the District of Puerto Rico pursuant to 28 U.S.C. Section 1391. The consumer plaintiffs purchased and consumed the ReNu brand contact-lens solution product object of this action in the District of Puerto Rico. The Defendant also engaged in the breaches object of this action in this judicial district.

4. Plaintiffs demand trial by jury.

II. THE PARTIES

5. The plaintiffs are: (1) ENERY FERNANDEZ PIÑERO, her husband GERARDO SUAREZ MERCADO, and the LEGAL CONJUGAL PARTNERHISP formed by them; (2) JOSE DAVID PEDROGO, his wife NEIDA DE-LAJARA BORELLI, and the LEGAL CONJUGAL PARTNERHISP formed by them; (3) MARIA ADORNO DÁVILA; (4) MANUEL CLASS CASTRO and the LEGAL CONJUGAL PARTNERHISP formed by him and his wife; (5) JUAN CARLOS PEREZ RUIZ his wife OMAYRA RIOS MUNOZ and the LEGAL CONJUGAL PARTNERHISP formed by them; (6) ROLANDO PEREZ VARGAS and his mother SONIA VARGAS PEREZ; (7) OSCAR PEREZ VARGAS and his mother SONIA VARGAS PEREZ; (8) LUISA VEGA RAMOS, her husband JAVIER MARTINEZ CORTES and the LEGAL CONJUGAL PARTNERHISP formed by them; (9) YARITZA VILLEGAS DIAZ; (10) HIRAM MALDONADO and MARGARITA HEREDIA on their own and on behalf of their minor daughter HIRMAR MALDONADO HEREDIA; (11) LILLIAM TRISTANI RODRIGUEZ; (12) MADELINE CALDERON COLON; (13) ADALYZ RODRIGUEZ PIZARRO her husband NELSON RODRIGUEZ and the LEGAL CONJUGAL PARTNERHISP formed by them; (14) MAGDALENA RODRIGUEZ RAMOS on her own and on behalf of her minor daughter FRANCYS PEREZ RODRIGUEZ; (15) EDGARDO ROBLES DAVILA, his wife RUTH BIDOT BAERGA and the LEGAL CONJUGAL PARTNERHISP formed by them; (16) ELISA PEDROZA GOMEZ, her husband ANGEL RIVERA RODRIGUEZ and the LEGAL CONJUGAL PARTNERHISP formed by them; (17) MAYRA GOMEZ TORRES her husband LUIS VELAZQUEZ ALAMO and the LEGAL CONJUGAL PARTNERHISP formed by them; (18) RAFAEL RIVERA SANCHEZ; (19) MARIELA FRIAS

APONTE her husband JOSE TORRES GONZALEZ and the LEGAL CONJUGAL PARTNERHISP formed by them; (20) GIOVANNI MARCANO MORAN his wife MAYRA CABRERA BATISTA and the LEGAL CONJUGAL PARTNERHISP formed by them; (21) WILMA MIRANDA PEÑA; (22) ELBA DAVID PEDROGO, her husband RAMÓN MATOS RIVERA and the LEGAL CONJUGAL PARTNERHISP formed by them; (23) JUAN CANCEL MONTES, his wife JENNIFFER ORTIZ and the LEGAL CONJUGAL PARTNERHISP formed by them;(24) ALBERTO DE HOWITT PEREZ; (25) LYDIA CRESPO RUIZ; (26) YOCELYN GONZALEZ CRESPO; (27) MIGDALIA GUADALUPE HERNANDEZ; (28) EILEEN MARQUEZ CASTILLO, her husband SEBASTIAN INSANZON and the LEGAL CONJUGAL PARTNERHISP formed by them; (29) HENRY MEDINA ATECA; (30) JOEL RIVERA RIVERA; (31) EVANGELINA RODRIGUEZ FELICIANO, her husband RICHARD GUZMAN RIVERA and the LEGAL CONJUGAL PARTNERHISP formed by them; (32) ROSA SANTOS CRUZ; (33) CARINA VAZQUEZ ESCODA, and her consensual companion RICARDO DIAZ CRUZ; (34) ENID MALAVE CRUZ, and her consensual companion HECTOR PEDROSA LUNA.

6. The plaintiffs are the consumers injured by the defective ReNu product manufactured, labeled, marketed and distributed by the defendant, as alleged herein below, and the immediate relatives related by marriage, blood and/or affinity to the consumer plaintiffs.

7. The consumer plaintiffs are: (1) ENERY FERNANDEZ PIÑERO; (2) JOSE DAVID PEDROGO; (3) MARIA ADORNO DÁVILA; (4) MANUEL CLASS CASTRO; (5) JUAN CARLOS PEREZ RUIZ; (6) ROLANDO PEREZ VARGAS; (7)

OSCAR PEREZ VARGAS; (8) LUISA VEGA RAMOS; (9) YARITZA VILLEGAS DIAZ; (10) HIRMAR MALDONADO HEREDIA; (11) LILLIAM TRISTANI RODRIGUEZ; (12) MADELINE CALDERON COLON; (13) ADALYZ RODRIGUEZ PIZARRO; (14) FRANCYS PEREZ RODRIGUEZ; (15) EDGARDO ROBLES DAVILA; (16) ELISA PEDROZA GOMEZ; (17) MAYRA GOMEZ TORRES; (18) RAFAEL RIVERA SANCHEZ; (19) MARIELA FRIAS APONTE; (20) GIOVANNI MARCANO MORAN; (21) WILMA MIRANDA PEÑA; (22) ELBA DAVID PEDROGO (23) JUAN CANCEL MONTES; (24) ALBERTO DE HOWITT PEREZ; (25) LYDIA CRESPO RUIZ; (26) YOCELYN GONZALEZ CRESPO; (27) MIGDALIA GUADALUPE HERNANDEZ; (28) EILEEN MARQUEZ CASTILLO; (29) HENRY MEDINA ATECA; (30) JOEL RIVERA RIVERA; (31) EVANGELINA RODRIGUEZ FELICIANO; (32) ROSA SANTOS CRUZ; (33) CARINA VAZQUEZ ESCODA; (34) ENID MALAVE CRUZ.

8. The other plaintiffs are the immediate relatives related by marriage, blood and/or affinity to the consumer plaintiffs.

9. All the plaintiffs are residents and citizens of, and, have their domicile in the Commonwealth of Puerto Rico.

10. The defendant is BAUSCH & LOMB, INCORPORATED (hereinafter referred to as “BAUSCH & LOMB” OR Defendant).

11. BAUSCH & LOMB is incorporated under the laws of the State of New York and has its principal place of business located at One Bausch & Lomb Place, Rochester, New York 14604-2701.

12. At the times relevant herein, BAUSCH & LOMB was engaged in the business of manufacturing, marketing, distributing,

promoting, testing, labeling and/or selling eye health products, including the ReNu brand contact-lens solution product, hereinafter also referred to as the ReNu product.

13. BAUSCH & LOMB does business worldwide and does substantial business in Puerto Rico.

14. BAUSCH & LOMB's revenues for the year 2004 were $2.2 billion.

15. At all times relevant hereto, BAUSCH & LOMB manufactured, labeled, marketed, sold, distributed, promoted, or otherwise brought the manufacturing and distributing of the ReNu brand contact-lens solution product into Puerto Rico.

16. BAUSCH & LOMB conducted, either by itself, or through its agents, business transactions within Puerto Rico, and it also participated, either by itself or through its agents, in the commission of the tort object of this complaint within Puerto Rico.

17. BAUSCH & LOMB breached its duty to put a defect free product in the Puerto Rico market. Defendant also breached its duty to put a safe product in the Puerto Rico market, through the negligent acts and/or omissions described herein below.

III. FACTUAL ALLEGATIONS

18. This case involves the ReNu brand contact-lens solution product, which was researched, designed, developed, manufactured, labeled, marketed, promoted, advertised, sold and distributed by

BAUSCH & LOMB as a multi purpose solution for the storing, cleaning, disinfecting, and wetting of soft contact lenses.

19. At the times relevant herein, the ReNu brand contact-lens solution product was being manufactured at the BAUSCH & LOMB's U.S. factory, located in Greenville, S.C.

20. An FDA inspection of the Greenville plant conducted between May 20 and June 10, 2002, revealed several significant quality-control deviations from the Quality System Regulation (QSR) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820, that the agency detailed in a letter of warning, dated July 17, 2002, to BAUSCH & LOMB.

21. The FDA found in its inspection, among other things, that BAUSCH & LOMB deviated from its duties because it:

A. "[F]ailed to appropriately validate the manufacturing processes currently utilized for all of [its] device products." According to the FDA, the "facility could not provide adequate documentation to establish a high degree of assurance that all of [its] manufacturing processes were effective and could consistently produce a product meeting its predetermined specifications and quality attributes, in accordance with 21 CFR 820.75." Further, "the facility continue[d] to have out-of-specification (OOS) results in finished

product testing for appropriate amounts [redacted] in the preservative/disinfectant used in the majority of [its] eye care products."

B. "[F]ailed to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, in accordance with 21 CFR 820.80(d)." Portions of lots were found to "have been released when testing revealed OOS levels of [redacted] in the finished product." "This partial release [was] based on limited testing performed on product until acceptable levels are found in the packaged product."

C. "[F]ailed to develop, control, and monitor production processes to ensure that [its] devices conform to their specifications, in accordance with 21 CFR 820.70." Further, the facility had "failed to establish and maintain procedures to adequately control environmental conditions, or other sources of contamination, which could reasonably be expected to have an adverse effect on product quality." The FDA specifically found that "lots of sterile eye care products" had been manufactured

"in rooms later found to have paint flaking from the ceiling grids".

D. "[F]ailed to adequately investigate the cause of this nonconformity, which directly related to product quality, and identify appropriate actions needed to correct and prevent recurrence of these quality problems, in accordance with 21 CFR 820.100."

E. "[F]ailed to establish and maintain appropriate procedures for the acceptance of incoming product to assure conformance to specified requirements, in accordance with 21 CFR 820.80."

22. Notwithstanding the FDA's warning letter, BAUSCH & LOMB continued to manufacture the ReNu brand contact-lens solution product in the same defective manner as before, causing thereby, among other things, the manufacturing and distribution of defective finished ReNu products into Puerto Rico that:

A. Contain out-of-specification ingredient amounts and/or a defect in its chemical composition.

B. Contain, among others, inappropriate amounts of the preservative/disinfectant ingredients.

C. Contain environmental and other sources of contamination, which could reasonably be expected

to have an adverse effect on product safety and quality, cause eye infection and injury.

23. On or around September, 2005, the Hong Kong's government alerted BAUSCH & LOMB that a serious kind of fungal eye infection was afflicting soft contact lens users that used the ReNu brand contact-lens solution product.

24. This infection was found to be a fungal *keratitis* caused by the *Fusarium* fungus, which may cause serious eye injury, including the risk of vision loss and corneal damage.

25. Some of the signs or symptoms of *keratitis* are unusual redness, eye pain, tearing, discharge, sensitivity to light and cornea inflammation.

26. The fungal infection can require prolonged drug therapy with antifungal medication. Those infected with fungal keratitis who do not receive or who do not respond to medical treatment may experience significant loss of vision and will usually require surgical intervention, including a corneal transplantation.

27. Studies by the Asian government "found a strong association between corneal infection and the use of ReNu solution."

28. In February 2006, BAUSCH & LOMB suspended sales of its ReNu product in Singapore and Hong Kong, pending investigation, after multiple reports linked the increase in incidents of *Fusarium keratitis* to the contact lens users consuming its product and in

response to requests made by the Asian government officials for it to pull the product out of the market.

29. Notwithstanding its knowledge about the serious fungal eye infections potentially associated with the ReNu brand contact-lens solution product, Defendant breached its duty to immediately withdraw its ReNu product from its other markets and/or to communicate said known potential health risks to its customers in the Continental U.S., and Puerto Rico and/or to advise them about the proper safety precautions to be taken in the use of the product.

30. On April 10, 2006, the CDC reported that as of April 9, 2006, 109 cases of suspected *Fusarium keratitis* were under its investigation and other public health authorities in 17 states of the U.S. Out of the 109 cases, 30 had been fully investigated. Out of the 30 fully investigated cases, 28 of the patients wore soft contact lenses. Out of those 28, 26 (93%) remembered which solution they used during the month before infection onset or had retained the actual bottle. All of these 26 ***(100%)*** reported using the ReNu product.

31. On April 10, 2006, the FDA and the CDC issued a news report to the healthcare practitioners alerting them about this serious fungal infection of the eye in soft contact lens wearers in the U.S.

32. On April 13, 2006, Defendant announced that it was withdrawing the ReNu product from the market, but still left it up to retailers to decide what to do with the lens products left on their shelves, and, largely, to health authorities to communicate to its customers about the product's risks and precautions.

33. Up to the present, there are at least 27 cases reported in Puerto Rico of consumers that have developed this serious fungal eye infection and/or other fungal or bacterial eye infections due to the use of the ReNu product which have caused them corneal ulceration and damage. Four of them have already lost the cornea and one has been submitted to a corneal transplant.

34. In all cases of reported fungal and/or bacterial eye infection in Puerto Rico the injured persons had been using the ReNu product.

35. The consumer plaintiffs purchased and used in Puerto Rico the defective ReNu product manufactured, labeled, marketed and distributed by BAUSCH & LOMB following the product's instructions and use recommendations.

36. The consumer plaintiffs would have not purchased and/or used the ReNu product had they known that it was defective or that it could cause a fungal and/or bacterial eye infection.

37. The use of the defective ReNu product adequately caused the consumer plaintiffs to develop a serious eye fungal and/or bacterial infection, which manifested with symptoms, such as:

unusual redness, eye pain, cornea inflammation and damage, tearing, discharge, and sensitivity to light.

IV. LIABILITY COUNTS

COUNT ONE: STRICT LIABILITY

38. The paragraphs stated hereinabove are literally incorporated herein and are made part of this paragraph.

39. BAUSCH & LOMB is strictly liable for the damages caused to the consumer plaintiffs because:

A. Defendant manufactured, labeled, marketed and distributed the ReNu product.

B. The ReNu product was expected to and did reach the consumer plaintiffs without substantial change in its condition as manufactured, labeled, marketed and distributed by Defendant.

C. The ReNu product manufactured, labeled, marketed and distributed by Defendant was defective in its chemical composition and/or due to contamination.

D. The ReNu product defect made its use unreasonably dangerous at the time it was placed in the stream of commerce because it could foreseeably cause fungal keratitis and/or other fungal or bacterial eye infections, loss of vision, corneal inflammation and damage. These health hazards made the ReNu product unsafe and unreasonable dangerous,

inasmuch it could foreseeably cause serious eye injury, infection and even total blindness to its users.

E. The consumer plaintiffs used the ReNu product because they were unaware of all the possible health hazards that it could cause to its users. The consumer plaintiffs could not have reasonably discovered the dangerous and hazardous nature of the product.

F. The usage to which the ReNu product was being put by the consumer plaintiffs was reasonably foreseeable and the intended use of the product.

G. The use of the ReNu product was the adequate and proximate cause of the consumer plaintiffs' eye injuries.

40. As a direct and proximate result of defendant BAUSCH & LOMB's negligent and/or wanton acts and/or omissions, the plaintiffs suffered the damages claimed herein below.

COUNT TWO: STRICT LIABILITY - FAILURE TO WARN

41. BAUSCH & LOMB is also strictly liable for the damages caused to the plaintiffs due to its failure to warn because:

A. Defendant knew, or should have known, at least since September 2005, that its ReNu product was

being linked to, and was the most likely cause of serious fungal and/or bacterial eye infection.

B. The consumer plaintiffs were unaware that the use of the ReNu product conveyed the risk of serious fungal and/or bacterial eye infection.

C. The ReNu product was unsafe and unreasonable dangerous, inasmuch it could foreseeably cause serious eye injury, infection and even total blindness to its users.

D. Defendant failed to warn its costumers that the ReNu product had been linked to, and was the most likely cause of serious fungal and/or bacterial eye infection, and, that it had been removed from the Asian market.

E. The usage to which the ReNu product was being put by the consumer plaintiffs was reasonably foreseeable and the intended use of the product.

F. Had the consumer plaintiffs known about the ReNu product's risks of serious eye infection they would have not purchased and/or used the product.

G. Defendant's failure to warn about the known risks of the use of its ReNu was the adequate and proximate cause of the consumer plaintiffs' eye injuries.

42. As a direct and proximate result of BAUSCH & LOMB's negligent and/or wanton acts and/or omissions, the plaintiffs suffered the damages claimed herein below

COUNT THREE: FAULT AND NEGLIGENCE

43. The paragraphs stated hereinabove are literally incorporated herein and are made part of this paragraph.

44. BAUSCH & LOMB is liable for the damages caused to the consumer plaintiffs because its fault and/or negligence.

45. BAUSCH & LOMB had the duty to use reasonable care in manufacturing, designing, testing, labeling, packaging, supplying, marketing, selling, advertising, warning and otherwise distributing the ReNu product.

46. BAUSCH & LOMB breached the aforementioned duties, through the following negligent and/or wanton acts and/or omissions:

A. Failing to use reasonable care to adequately and properly make tests, inspections, trials and/or evaluations necessary to discover the defects and unreasonably dangerous risks of fungal and/or bacterial eye infection associated with the ReNu product. Had defendant performed adequate testing and inspection, the same would have shown that the ReNu product was defective in its chemical composition and/or due to contamination, and, that

it posed serious risk of fungal and/or bacterial eye infection.

B. Failing to use reasonable care to ascertain that that ReNu product was not safe and proper for the purpose for which it was designed, manufactured and sold.

C. Failing to use reasonable care to utilize and/or implement a reasonably safe formula design and manufacture of the ReNu product. As a result thereof, BAUSH & LOMB designed, manufactured and distributed to its foreseeable users an unreasonably dangerous, hazardous and defective product.

D. Failing to use reasonable care to manufacture a safe ReNu product for the use for which it was intended.

E. Failing to use reasonable care to adequately and properly warn the plaintiffs and other consumers purchasing the ReNu of the known significant risks of causing fungal and/or bacterial eye infection and corneal damage.

F. The warnings given by Defendant did not accurately reflect the existence of the known fungal and/or bacterial eye infection risks, nor the known

incidence, symptoms, scope or severity of the foreseeable eye injuries.

G. Failing to use reasonable care to properly label the ReNu's warnings and to do so in Spanish, in order to warn the plaintiffs and other consumers of the serious fungal and/or bacterial eye infection risks, complications and injury that could be caused by the consumption of the ReNu product.

H. Failing to use reasonable care to comply with standards of care, including accepted industry standards, FDA recommendations, government regulations and statutes, in the design, manufacture, affixing of warnings, and otherwise production and distribution of the ReNu product.

I. Failing to comply in the manufacturing of the ReNu product with the Quality System Regulation (QSR), as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 820.

J. Failing to use reasonable care to timely remove and/or recall from the market, retrofit, and/or otherwise prevent the continued consumption by the plaintiffs of the defective and unreasonably dangerous ReNu product.

K. The intentional manipulation of available scientific data to cover up the known serious fungal and/or bacterial eye infection dangers caused by the ReNu product, coupled with a false and misleading aggressive promotional campaign which intentionally omitted adverse risk information and knowingly misrepresented the ReNu product to be a safe product.

L. Defendant's negligent and/or wanton acts and/or omissions were the adequate and proximate cause of the consumer plaintiffs' eye injuries.

47. As a direct and proximate result of BAUSCH & LOMB's negligent and/or wanton acts and/or omissions, the plaintiffs suffered the damages claimed herein below.

COUNT FOUR: FRAUD

48. The paragraphs stated hereinabove are literally incorporated herein and are made part of this paragraph.

49. BAUSCH & LOMB's advertisements and promotional materials relating to the use of the ReNu product, as well as its product labels, were misleading and had a tendency to deceive the plaintiffs and other consumers because they:

A. Failed to disclose the material fact that the ReNu product was defective and possessed potential risks of causing serious eye fungal and/or bacterial infections.

B. Failed to disclose the material fact that the reported incidence of serious fungal and/or bacterial eye infection injury was being linked to the use of the ReNu product.

C. Failed to disclose the material fact that the reported incidence of serious fungal and/or bacterial eye infection injury linked to the use of the ReNu product had forced the withdrawal of the product from the Asian market since February 2006.

D. Failed to inform in Spanish to its consumers in Puerto Rico about these foreseeable eye fungal and/or bacterial infection risks.

50. Such promotional materials, advertisements and product labels used by Defendant in the marketing, sale and labeling of the ReNu product did not provide sufficient warnings, information and instructions in the English and Spanish languages that would have put the plaintiffs and other consumers on notice as to the dangers and adverse side effects from the use of the ReNu product.

51. As a direct and proximate result of BAUSH & LOMB's fraud and suppression, the plaintiffs suffered the damages claimed herein below.

COUNT FIVE: BREACH OF EXPRESS WARRANTY

52. The paragraphs stated hereinabove are literally incorporated herein and are made part of this paragraph.

53. Defendant expressly warranted to the plaintiffs and other consumers, by and through statements made by BAUSH & LOMB or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials, that the ReNu product was safe, effective, fit and proper for its intended use.

54. In using the ReNu product, the plaintiffs relied on the skill, judgment, representations and foregoing express warranties of Defendant. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended.

55. As a direct and proximate result of BAUSH & LOMB's breaches of express warranties, the plaintiffs suffered the damages claimed herein below.

COUNT SIX: BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

56. The paragraphs stated hereinabove are literally incorporated herein and are made part of this paragraph.

57. BAUSH & LOMB breached the implied warranty of merchantability: BAUSH & LOMB sold the ReNu product. The ReNu product was used by the plaintiffs for the ordinary purposes for which such products are used. BAUSH & LOMB's product was defective and unmerchantable, i.e., not fit for the ordinary purposes for which such products are used.

58. As a direct and proximate result of BAUSH & LOMB's breach of its implied warranty of merchantability, the plaintiffs suffered the damages claimed herein below.

COUNT SEVEN: BREACH OF THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

59. The paragraphs stated hereinabove are literally incorporated herein and are made part of this paragraph.

60. BAUSH & LOMB breached the implied warranty of fitness for a particular purpose: BAUSH & LOMB designed, manufactured and sold the ReNu product. BAUSH & LOMB knew, or had reason to know, of the particular purpose for which the product was to be used. The plaintiffs and other consumers were and are unskilled in the research, design and manufacture of the ReNu product and reasonably relied entirely on the skill, judgment and implied warranty of Defendant in using the ReNu product. Defendant knew, or had reason to know, that the plaintiffs and other consumers were relying on its skill and judgment to select or furnish a suitable product for the intended purpose. The ReNu product was used by the consumer plaintiffs for the particular purpose for which the selection had been made by Defendant. The ReNu product was not reasonably fit and suitable for the use for which it was selected, in that it had dangerous propensities when put to its intended use.

61. As a direct and proximate result of BAUSH & LOMB's breach of its implied warranty of fitness for a particular purpose, the plaintiffs suffered the damages claimed herein below.

COUNT EIGHT: OBSTINACY AND ATTORNEY'S FEES

62. The paragraphs stated hereinabove are literally incorporated herein and are made part of this paragraph.

63. Should Defendant obstinately and temerariously deny liability and/or responsibility for the amounts claimed in this complaint, the plaintiffs would be entitled to an award of prejudgment interest, to be computed from the amount finally adjudged to them, plus reasonable attorneys' fees.

V. DAMAGES COUNTS

FIRST CAUSE OF ACTION

64. The paragraphs stated hereinbefore are literally incorporated herein and are made part of this paragraph.

65. As a direct consequence of Defendant's breaches, faults and/or negligent acts and/or omissions detailed herein above, the consumer plaintiffs developed a serious eye fungal and/or bacterial infection.

66. The fungal and/or bacterial eye infection, and its related symptoms and complications have caused and will continue to cause the consumer plaintiffs to sustain eye pains, vision limitations, loss of vision, unusual eye redness, tearing, discharge and sensitivity to light and corneal ulceration, scarring and/or injury, and severe headaches.

67. The fungal and/or bacterial eye infections have required prolonged drug therapy with antifungal and/or antibacterial

medication and/or eye injections. The treatment has been painful and annoying, and eye infections have persisted and continued to cause injury and damages notwithstanding the provided medical treatment.

68. The fungal and/or bacterial eye infections have also caused upon the consumer plaintiffs the actual loss of eyesight or the ongoing worry of loosing their eyesight or cornea, or of having to undergo surgical eye interventions and/or corneal transplants.

69. As direct result of the above stated physical injuries, disabilities and limitations, the consumer plaintiffs have also suffered and will continue to suffer from severe mental, moral and emotional damages, pains, anguish and distress, including irritability, anxiety, depression, insomnia and other related symptoms.

70. As direct consequence of the above stated physical, mental and emotional injuries and limitations, the consumer plaintiffs have come to be substantially impaired in their general physiological functions and in their capacity to engage in work, social and family activities; and, they have sustained a loss of their capacity to enjoy life.

71. The consumer plaintiffs are each entitled to receive as full, just and fair compensation for the aforementioned damages a reasonable sum of money in an amount of no less than **ONE MILLION DOLLARS ($1,000,000)**.

SECOND CAUSE OF ACTION

72. The paragraphs stated herein before are literally incorporated herein and are made part of this paragraph.

73. As direct result of the physical, mental and emotional damages, disabilities and limitations sustained by the consumer plaintiffs, either themselves or the LEGAL CONJUGAL PARTNERSHIPS constituted by them and their respective spouse, have had to incur and will continue to incur in expenses for medical care, treatment and medications, rehabilitation and monitoring; and, they have also sustained and will continue to sustain loss of income.

74. Each consumer plaintiffs or the LEGAL CONJUGAL PARTNERSHIP constituted by each and his or her respective spouse is entitled to receive as full, just and fair compensation for the aforementioned losses and damages a reasonable sum of money in an amount of no less than **TWENTY FIVE THOSAND DOLLARS ($25,000)**.

THIRD CAUSE OF ACTION

75. The paragraphs stated herein before are literally incorporated herein and are made part of this paragraph.

76. As direct result of the physical, mental and emotional injuries, disabilities and limitations sustained by the consumer plaintiffs, their spouses and/or the other plaintiffs related to them by blood or affinity have sustained and will continue to sustain severe mental, moral and emotional pain, anguish and

distress, loss of companionship, care and affection, and loss of the capacity to enjoy life.

77. These related plaintiffs are each entitled to receive as full, just and fair compensation for the aforementioned damages a reasonable sum of money in an amount of no less than **TWO HUNDRED FIFTY THOUSAND DOLLARS ($250,000.00)**.

VI. PRAYER FOR RELIEF

WHEREFORE, it is respectfully requested that Judgment be entered by this Honorable Court in favor of the plaintiffs and against Defendant:

A. Granting the plaintiffs all the sums requested in the complaint;

B. Imposing upon Defendant the payment of all costs and expenses to be incurred in this lawsuit;

C. Granting the plaintiffs any other relief that they may be entitled to as a matter of law; and,

D. Awarding the plaintiffs pre-judgment, plus a reasonable amount for attorney's fees.

RESPECTFULLY SUBMITTED, in San Juan, Puerto Rico, this 12th day of January, 2007.

I HEREBY CERTIFY I HEREBY CERTIFY, that on this date I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

S/ Eric M. Quetglas Jordan

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